K130163

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92(c).

Date: July 19, 2013

AUG 16 2013

1. Company and Correspondent making the submission:

	Company
Name	Diadent Group International
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Phone	+82 43-266-2315
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Contact	Gil Jun, Hong

2. Device:
   Proprietary Name: D-LUX
   Common Name: Dental visible light curing unit
   Classification Name – Ultraviolet activator for polymerization

3. Predicate Device:
   Cybird LED Curing Light, K042703

4. Classifications Names & Citations:
   EBZ, 872.6070

5. Description:
   The D-Lux is a cordless LED curing light, which is intended to polymerize (set) resinous dental pit and fissure sealants or restorative materials by transmission of light through a rod. It is portable and battery rechargeable.

6. Indication for use:
   The D-LUX is intended to polymerize resinous dental materials, restorative

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composite materials, and orthodontic brackets, bonding and sealing materials that are photo-polymerized in the 420~490nm waveband of visible light.

7. Review:

The D-LUX has the same device characteristics as the predicate device, the Cybird LED Curing Light; indication, material, design and use concept are similar.

The D-LUX conforms to IEC 60601-1 Medical electric equipment, Part 1: General requirements for safety and IEC 60601-1-2 Medical electric equipment, General requirements for safety collateral standard electromagnetic compatibility, ISO 4049 and ADA 48[2009] Visible light curing units. The testing result on the depth of cure by ISO 4049:2000 shows the substantially equivalence – D-Lux (new device) 2.91mm and Cybird (predicate device) 2.97mm.

Based on the comparison of intended use and technical features, the D-LUX is substantially equivalent to the predicate device.

8. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Diadent Group International Inc. concludes that the D-LUX is safe and effective and substantially equivalent to predicate devices as described herein.

9. Diadent Group International will update and include in this summary any other information deemed reasonably necessary by the FDA.

END

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 16, 2013

Diadent Group International
C/O Mr. Ned Devine
Responsible Third Party Official
Underwriters Laboratories, Incorporated
333 Pfingsten Road
Northbrook IL 60062

Re: K130163
Trade/Device Name: D-LUX
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: July 31, 2013
Received: August 7, 2013

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K K130163

Device Name: D-LUX

Indication for use:

The D-Lux is intended to polymerize resinous dental materials, restorative composite materials, and orthodontic brackets, bonding and sealing materials that are photo-polymerized in the 420-490nm waveband of visible light.

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21CFR801 Subpart D) (Per 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA
Mary S. Runner -S
2013.08.16
15:18:56 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Respiratory, Infection Control and
Dental Devices
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